IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Yves BONHOMME et al.

Serial No.: Group Art Unit: 1615

Filed: March 25, 2004 Examiner: Susan T. TRAN

For: SOLID ORAL DOSAGE FORM COMPRISING A COMBINATION OF METFORMIN AND GLIBENCLAMIDE

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

Timing and Fees

☒ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:

- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
- ☐ within three months of the actual filing date of the national phase of a PCT application; OR
- ☒ before the mailing of a first substantive office action (including after filing of an RCE).

☐ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:

- ☐ a final rejection under 37 C.F.R. 1.113;
- ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
- ☐ a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR

☐ a check covering the fee of $180.00 under 37 C.F.R. § 1.17(p).

☐ Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:

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☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR

☐ a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

☐ the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of $180.00 under 37 C.F.R. § 1.17(p).

Statements Under 37 C.F.R. 1.97(e)

☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or

☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

Cited Materials

☒ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. 10/329,426, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).

☐ Copies of materials listed but not attached were cited in an international search report dated _____.

☐ Copies of the materials listed are attached (except for the foregoing).

Non-English Language References

☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).

☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

X = document of particular relevance when it is taken alone
Y = document of particular relevance when it is combined with another such document
A = document defining the general state of the art
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P = intercalated document
T = document cited to understand the theory or principle underlying the invention
E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date
D = cited in the application
L = cited for another reason
& = publication of member of same patent family

☐ Translation of other relevant information on foreign search report

[insert necessary translation here]

Other Information

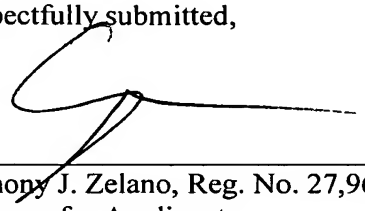
Payment of Fees Due (If Any):

☐ A check for $_____ covering the fee identified above is attached.

☐ Please charge to Deposit Account No. 13-3402 $_____ for the fee identified above.

☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



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Attorney Docket No.: MERCK-2593-R1-C1

Date: March 25, 2004

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 3

Complete if Known	
Application Number	
Filing Date	March 25, 2004
First Named Inventor	Yves BONHOMME et al.
Group Art Unit	1615
Examiner Name	Susan T. TRAN
Attorney Docket Number	MERCK-2593-R1-C1

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (*if known*)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
	A1	3,979,520		ROTHE et al.	09/1976
	A2	6,544,564		FARLEY	04/2003
	A3	5,922,769		BARELLI et al.	07/1999
	A4	5,965,584		IKEDA et al.	10/1999
	A5	5,663,198		REUL et al.	09/1997
	A6	5,631,224		EFENDIC et al.	05/1997
	A7	4,916,163		NI	04/1990
	A8	4,060,634		ROTHE et al.	11/1997
	A9	3,174,901		STERNE	03/1965

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	Kind Code[5] (*if known*)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	B1	WO	97/17975		BARELLI et al.	05/1997		
	B2	WO	98/57634			12/1998		
	B3	WO	97/17975			05/1997		
	B4	DE	0 362 703			04/1990		

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T [2]
	C1	Bi-Euglucon M Italian Package Insert, Repertorio Farmaceutico Italiano, 1998 (with English translation pp. 1-9)	
	C2	R. Vigneri, et al., Diabete & Metabolisme, vol. 17, pp. 232-234, "Treatment of NIDDM Patients With Secondary Failure to Glyburide: Comparison of the Addition of Either Metformin or Bed-Time NPH Insulin to Glyburide", 1991	
	C3	Linda Higginbotham, et al., The Medical Journal of Australia, pp. 154-156, "Double-Blind Trial of Metformin in the Therapy of Non-Ketotic Diabetics", Aug. 11, 1979	
	C4	Iris J. Edwards, et al., Diabetes, vol. 46, No. 5, Suppl. 1, pp. 45A, "Combination Glipizide Gits/Metformin Treatment Reduces Low Density Lipoprotein Binding To Arterial Proteoglycans In NIDDM", 1997	
	C5	William T. Cefalu, et al., Diabetes, vol. 45, Suppl. 2, pp. 201A, "Combination Glipizide Gits/Metformin Normalizes Glucose And Improves Insulin Sensitivity In Hyperinsulinemic Moderately Well Controlled NIDDM", 1996	
	C6	John R. Crouse, et al., Circulation, vol. 94, No. 8, Suppl. 1508, Effects Of Combination Glipizide Gits/Metformin Treatment On Oxidizability Of LDL In Non-Insulin Dependent Diabetes Mellitus, 1996	
	C7	W. T. Cefalu, et al., Diabetologia, vol. 39, Suppl. 1, pp. A231, "Insulin Sensitivity Is Improved After Glipizide Monotherapy And Combination With Metformin", 1996	
	C8	Gerald M. Reaven, et al., Journal of Clinical Endocrinology and Metabolism, vol. 74, No. 5, pp. 1020-1026, Combined Metformin-Sulfonylurea Treatment Of Patients With Noninsulin-Dependent Diabetes In Fair To Poor Glycemic Control, 1992	
	C9	CB Hollenbeck, et al., Diabetes, vol. 39, Suppl. 1, pp. 108A, "Combination Glipizide/Metformin Treatment In Non-Insulin Dependent Diabetes (NIDDM)", 1990.	
	C10	Press Release Sep. 30, 1999: Bristol-Myers Squibb Files New Drug Application for Novel Oral Antidiabetic Drug, 2 pp., 1999.	
	C11	Glucomide--Italian Package Insert, Repertorio Farmaceutico Italiano, 1 p., 1999 (with English translation pp. 1-6).	
	C12	Glibomet--Italian Package Insert, Repertorio Farmaceutico Italiano, 1 p., 1999 (with English translation pp. 1-7).	
	C13	Suguan M--Italian Package Insert, Repertorio Farmaceutico Italiano, 1 p., 1999 (with English translation pp. 1-9).	

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T [2]
	C14	Bi-Euglucon M13 Italian Package Insert, Repertorio Farmaceutico Italiano, 1 p., (with English translation pp. 1-9).	
	C15	Blume et al., Drug Development and Industrial Pharmacy, 19(20), 2713-2741 (1993)	
	C16	PDR, 56 ed, 2002, "Alyburide" listing and Glucophage ® and Glucovance ® package inserts	
	C17	PDR, 52 ed, 1998, "Glyburide" listing, generic listings and Micronase ®, Glynase ® and Dia βeta® package inserts	
	C18	AU 42302/89 Abstract	
	C19	Al-Ahmed et al., "Bioscience Reports," Vol. 9, No. 3, 1989, 347-350.	
	C20	Letter dated April 1, 2002 from Ivax Pharmaceuticals, Inc. to Lipha, S.A. (assignee of U.S.P. 6,303,146) and Bristol-Myers Squibb (marketer of Glucovance ® covered by U.S.P. 6,303,146).	

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